

MEMORANDUM

SUBJECT: Summary of February 15, 2000 Meeting Between Wilfarm LLC, Schering Plough and OPP Regarding Pirimiphos-Methyl

FROM: Stephanie Willett, Team Leader
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Pirimiphos-methyl
Docket No. 34168

Attendees

EPA:	Susan Hanley (HED)	Others:	Ted Rogers (USDA/OPMP)
	Whang Phang (HED)		Bob Sielaty (Wilfarm)
	Lorilyn McKay (SRRD)		Dick Enders (Schering Plough)
	Christina Swartz (HED)		Linda Carlocke (Wilfarm)
	Jeff Dawson (HED)		
	Christine Olinger (HED)		
	Alan Halvorson (BEAD)		
	Stephanie Willett (SRRD)		

At the request of Wilfarm, a meeting was held regarding the reregistration of pirimiphos methyl. The registrant wanted to get an update on the reregistration schedule for the pesticide, and provide additional information on how pirimiphos-methyl is used.

OPP reviewed the current OP transparency process, and explained that pirimiphos-methyl would shortly enter phase 5 of the process where the public would have the opportunity to comment on the refined risk assessment and submit risk mitigation ideas. The registrants were informed that some interim decisions will be made regarding pirimiphos methyl before the end of calendar year 2000. A considerable amount of time was spent clarifying the adequacy and implications of the toxicity database. At the end of the discussion, it was clear that the toxicity database was less than adequate, and that the lack of some important studies had a negative impact on the human health risk estimates. Two major studies, a chronic dog study and a combined chronic/carcinogenicity rat study, remain outstanding. Additionally since the database did not include an acceptable dermal toxicity study, risk estimates for workers had to be based on

oral studies. The Agency scientists encouraged the registrant to conduct a 28-day dermal toxicity study in the rats for the purposes of refining the short and intermediate term dermal toxicity endpoints. The registrant(s) agreed to conduct additional studies in the near future. They were informed that some regulatory decisions would be made this year based on the current database. When asked to comment on considerations for new registrations such as the pour-on use that Schering Plough is pursuing, OPP indicated that no new uses could be entertained until after the current uses have been reassessed. The recent DCI for a developmental neurotoxicity study for pirimiphos methyl was briefly discussed, with Wilfarm indicating they had submitted a waiver request.

The registrant then showed two videos on grain and seed treatment application methods for the chemical. Questions were previously raised by the registrants and USDA regarding the appropriateness of some of the scenarios used to derive worker risk estimates. USDA stressed the importance of this chemical for use in on-farm grain and seed storage silos, and referenced recently enacted USDA policy to promote on-farm storage. At the conclusion of the video presentation, OPP concluded that the information in the videos confirmed their approach to estimating worker risk. The Schering-Plough representative indicated that minimal exposure is expected to workers handling ear tags since the pesticide is impregnated into plastic, and all agreed exposure and risk from the ear tag use is expected to be minimal.

The registrant left general information regarding the uses and benefits of pirimiphos-methyl, as well as diagrams of application equipment for the Agency to consider. The registrant stressed the current low volume use of the chemical in the U.S., the importance of its use in IPM programs, and the lack of alternatives for use on stored grain, noting especially the recent removal of the stored grain use of malathion due to resistance. They also noted the importance of pirimiphos-methyl in the International Community, noting a recent evaluation of the chemical by WHO, and its public health uses outside of the United States. USDA also noted the importance of use of seed protectants in indirectly reducing the presence of aflatoxin in stored grain.

cc: SRRD Files